

## **REMARKS/ARGUMENTS**

Claims 1-3, 6-10 and 12-13 are pending in the instant application. Favorable reconsideration of the present claims is kindly requested.

### **Petition to Withdraw Premature Finality**

The rejection of claim 13 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement is newly presented in the most recent Final Office Action. Claim 13, including the feature that the Office Action now avers lacks written description support, was first presented in an amendment filed January 7, 2009. The Office Action did not allege a lack of written description support in the subsequent Office Action mailed March 9, 2009. Rather, the issue is first raised in the most recent Office Action. However, claim 13 was not amended in Applicant's June 8, 2009 response. Therefore, the new rejection of claim 13 was not necessitated by Applicant's Amendment. Applicant has had no opportunity to respond to this new rejection of claim before the Office Action was made final.

Applicant respectfully submits that the rejection has therefore prematurely been made final, and kindly requests that the finality be withdrawn.

### **Rejection under 35 U.S.C. § 112**

Claim 13 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action alleges that the Application does not disclose a membrane lacking any preexisting opening therethrough. Applicant respectfully traverses the rejection, for at least the following reasons.

The test for sufficient written description is not an *ipsis verbis* test. *Martin v. Johnson*, 454 F.2d 746, 172 U.S.P.Q. 391 (CCPA 1972); M.P.E.P. § 2163(II)(A)(3)(a). The specification need only "describe the claimed invention so that one skilled in the art can recognize what is claimed." *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 69 USPQ2d 1886 (Fed. Cir. 2004). Moreover, the drawings themselves form part of the written description. "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, **figures, diagrams**, and formulas that fully set forth the claimed invention." M.P.E.P. § 2163(I) (citing *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997))(emphasis added).

In this case, Applicant kindly refers to Figs. 2a and 3 as originally filed. Membrane 17 is depicted in cross-section as a solid unit, *i.e.*, lacking any preexisting opening therethrough. Drawing convention among those skilled in the art would be to depict any such pre-existing opening. For example, and in contrast to Applicant's instant disclosure, the Wyatt reference clearly depicts the preexisting opening in its views (e.g., cross-sectional views, Figs. 6, 7). The most recent Office Action no longer alleges that a membrane lacking any preexisting opening therethrough is taught or suggested by Wyatt. The previous rejection of claim 13 as allegedly obvious is not repeated in the most recent Office Action, as is the case for claims 1-3, 7-10 and 12.

Therefore, Applicant respectfully submits that the application as original filed includes ample support for the feature of claim 13 "a first flexible air- and liquid-proof membrane lacking any pre-existing opening therethrough". Favorable reconsideration and withdrawal of the rejection is kindly requested.

#### **Rejection under 35 U.S.C. § 103**

Claims 1-3, 7-10 and 12 are rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,632,735 to Wyatt, *et al.* ("Wyatt"), in view of U.S. Patent No. 5,685,866 to Lopez ("Lopez"). Applicant respectfully traverses the rejection, for at least the following reasons.

As amended above, independent claims 1 and 12 are amended to recite that the first flexible membrane is a "first flexible non-split air- and liquid-proof membrane" (markup per 37 C.F.R. § 1.121). Applicant refers to Figs. 2a and 3 as providing support for this amendment. No new matter has been added.

The most recent Office Action withdraws the rejection of claim 13, acknowledging that Wyatt and/or Lopez do not teach or suggest, singly or in combination, "a first flexible air- and liquid-proof membrane lacking any pre-existing opening therethrough". As already noted, and implicitly acknowledged in the Office Action, Wyatt does not disclose a device comprising a non-split membrane. Instead, Wyatt discloses a device comprising a split septum (27 in figure 8A).

The structure recited in independent claims 1 and 12 provide a benefit to the user not obtainable by the purported combination of Wyatt and Lopez. If a membrane, such as the membrane (36) of the device disclosed by Lopez (Fig. 3) is held against the split septum of Wyatt's device with a pressure, the split in the split septum is able to be opened, and it may

thereby allow medical substance inside the device to leak out of the device. In contrast, the non-split membrane of the device according to the present invention is therefore not only used to keep the device sterile, but it is also used to prevent medical substance from leaking out of the device while a medical substance is being injected into the device via the device's non-split membrane.

It remains well-settled that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Therefore, independent claims 1 and 12 as amended are respectfully submitted as patentably distinguished over Wyatt and/or Lopez, taken singly or in combination.

Claims 2-3 and 7-10 each depend, directly or indirectly, from independent claim 1. These dependent claims are each separately patentable, but in the interest of brevity they are offered as patentable for at least the same reasons as their underlying independent base claim, the feature of which are incorporated by reference. Therefore, Applicant respectfully submits that the rejection have been obviated, and kindly requests favorable reconsideration and withdrawal.

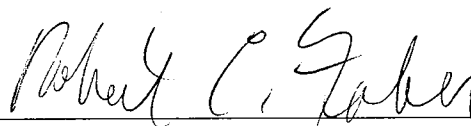
#### Conclusion

In light of the foregoing, Applicant respectfully submits that all claims are patentable, and further that the instant application is in condition for allowance. An early and favorable Notice of Allowability is kindly solicited.

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RCF/DJT:jh

Respectfully submitted,



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